MEDICAL MUTUAL®

Drug Policy

Policy:	Verzenio (abemaciclib)	Annual Review Date: 10/15/2020 Last Revised Date: 10/15/2020

OVERVIEW

Verzenio, a cyclin-dependent kinase (CDK) 4/6 inhibitor, is indicated in combination with Faslodex (fulvestrant intramuscular injection) for the treatment of women with hormone receptor positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy. Pre/postmenopausal women treated with Verzenio plus Faslodex should be treated with a gonadotropin-releasing hormone (GnRH) agonist according to current clinical practice standards. Verzenio is also indicated as monotherapy for the treatment of adult patients with HR+, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

POLICY STATEMENT

This policy involves the use of Verzenio. Prior authorization is recommended for pharmacy benefit coverage of Verzenio. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Verzenio as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Verzenio be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Verzenio must be prescribed by or in consultation with an oncologist or hematologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Verzenio is recommended in those who meet the following criteria:

1. <u>Breast Cancer</u>

Criteria. *Patient must meet the following criteria*

A. Patient has advanced or metastatic hormone receptor positive (HR+) [i.e. estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease; AND
B. Patient has human epidermal growth factor receptor 2 (HER2) negative breast cancer; AND
C. The patient meets one of the following criteria (a OR b):

a. The patient's breast cancer has progressed during or after endocrine therapy (e.g. anastrazole, exemestane, letrozole, tamoxifen, Fareston, exemestane plus Afinitor, Faslodex, megestrol acetate, fluoxymesterone, high-dose ethinyl estradiol); AND one of the following (i, ii, OR iii):
   - **i.** The patient is a male or a postmenopausal female and Verzenio will be used in combination with fulvestrant; OR
   - **ii.** The patient is premenopausal or perimenopausal and meets ALL of the following conditions (1 AND 2):
     1. The patient is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) agonist (e.g. Lupron, Trelstar, Zoladex); AND
     2. Verzenio will be used in combination with fulvestrant; OR
   - **iii.** Verzenio will be used as monotherapy AND the patient has had prior chemotherapy for treatment of metastatic breast cancer; OR

b. Verzenio will be used in combination with an aromatase inhibitor as initial endocrine-based therapy AND the patient meets ONE of the following (i OR ii):
   - **i.** The patient is a postmenopausal female; OR
   - **ii.** The patient is a male AND Verzenio will be used in combination with suppression of testicular steroidogenesis (e.g. using GnRH agonists such as leuprolide, triptorelin, or goserelin)

2. **<u>Another indication that is not listsed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation</u>**
   Criteria. *Prescriber will provide specific diagnosis for documentation*

3. **<u>Patient has been stared on Verzenio</u>**
   Criteria. *Approve for an indication or condition addressed as an approval in this document*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Verzenio tablets [prescribing information]. Indianapolis, IN: Eli Lilly and Company; March 2020.
2. Abemaciclib. In; DRUGDEX [online database]. Truven Health Analytivs; Greenwood Village, CO. Last updated15 September 2020. Accessed on 9 October 2020.
3. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 1.2018 – March 20, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on 21 October 2018.
4. The NCCN Drugs and Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on 9 October 2020.